

Research on Compulsory Patent License System and Practical Application

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Abstract: The article briefly reviews the development process of the patent compulsory licensing system, and briefly describes the implementation of the patent compulsory licensing system for medicines in Thailand in order to protect the public health interests of the country under pressure from developed countries. It is pointed out that the role of the patent compulsory licensing system in practice is to protect the interests of vulnerable groups in a reasonable manner without prejudice to the interests of patentee.

1. Introduction

The patent right granted to the patentee by law is a legitimate power of monopoly. But at the same time, in order to prevent arbitrary use of the patent right, it is necessary to impose necessary restrictions on the monopoly right. Among all these methods, the patent compulsory licensing system is a reasonable restriction on the way to exercise the patent right, which is an important to protect the public interest and prevent the arbitrary use of patent monopoly. In recent years, the spread of AIDS and the outbreak of pandemic infectious diseases, such as SARS and avian influenza, have made the world face a serious public health crisis, while less developed countries are facing the most serious public health crisis because of limited technology in the field of medicines and lack of authorized license for medicines from developed countries. However, due to the monopoly attitude of developed countries on medicines patents, the contradiction between medicines patents in developed countries and public health rights in developing countries is becoming increasingly serious. Therefore, the importance of compulsory license of patent right as a solution to this contradiction is self-evident. As a developing country, in general, the research on patent right in China started late. Although the legislation in the field of patent compulsory licensing system has been gradually improved, it is still a blank in the field of practice. This article aims to provide a legal basis and operating norms for the implementation of China's compulsory licensing system by studying the practice of typical national compulsory licensing systems.

2. Development of Patent Compulsory Licensing System

2.1. Paris Convention

The patent compulsory licensing system was first proposed in the first multilateral international convention on industrial property protection signed in 1883, namely “the Paris Convention for the Protection of Industrial Property” (hereinafter referred to as the Paris Convention). However, since the Paris Convention was the first patent compulsory licensing system, the related research was not mature enough, and the definitions of the basis of exclusive compulsory license and public interest were pretty vague. For example, the action of “not exploiting the patent” was regarded as the patentee’s abuse of the right, but there was no explanation on which specific actions were “the exploitation of the patent”. In order to strive for the best interests, the countries had serious differences on the stipulation of patent compulsory licensing system. Eventually, the Paris Convention gradually became a wrestle between developed and developing countries.

2.2. TRIPs Agreement

Since the 20th century, the protection of intellectual property rights had become a mainstream trend in the worldwide. Therefore, the first “Agreement on Trade-Related Aspects of Intellectual Property Rights” (hereinafter referred to as the TRIPs Agreement) that incorporated intellectual property protection into the world trading system provided an unprecedented protection mechanism for intellectual property in countries around the world. Meanwhile, in order to prevent patentee from abusing rights and adhere to the spirit of the Paris Convention, the TRIPs Agreement also stipulated a patent compulsory licensing system. Namely, under certain circumstances, such as for the benefit of public health, the state can authorize capable enterprises to produce patented products without authorization of patentee. However, in actual operation, the TRIPs Agreement does not properly balance the interests of patentee and patent applicants. The specific manifestation is excessively restricting patent applicants from applying to implement the patent compulsory licensing system. Therefore, the TRIPs Agreement is regarded as a mandatory and arbitrary rule which is imposed by developed countries on developing countries, without considering the interests of developing countries.

2.3. Declaration and General Council Resolution

Since the 21st century, global public health crises such as AIDS and bird flu occurred frequently. Although the TRIPs Agreement contained some public health exception clauses, there were many issues that needed to be clarified and explained. Therefore, it was imperative to revise the TRIPs Agreement. With the strong appeal and active promotion of developing countries, “The Doha Declaration on TRIPs Agreement and Public Health”(hereinafter referred to as the Doha Declaration) and the subsequent “Implementation of paragraph 6 of the Doha Declaration on the TRIPs Agreement and public health”(hereinafter referred to as the General Council Resolution) appeared. It can be said that the adoption of the Doha Declaration is a major progress in addressing the accessibility of patented medicines. However, the Doha Declaration still failed to completely eliminate the obstacles of the TRIPs Agreement to developing countries with insufficient medicines production capacity. Subsequently, the General Council Resolution removed the obstacles to importing patented medicines under the current patent protection system. It not only reduced the burden of developing countries in the public health crises on importing expensive patented medicines, but also improved their ability to respond public health crises.

3. Common Applications of Compulsory Patent Licensing System

3.1. Compulsory Licensing System in Medical Field

In the field of medicines, the research and application of biomedical technology are extremely important to public health issues. However, the patent protection system has limited the development of the medical industry and the effective use of these technologies. Medical patent is actually an exclusive private right, especially for the developed countries who have mastered the advanced technology of bio-making medicines. In order to ensure competitiveness and market position, they have extremely high protection for their own technology. However, the social public health right that relies on the medical patent is a public right. Especially when a social public health crisis occurs in developing countries, medical patent right and public interest will fall into conflict. Meanwhile, as for the manufacturers with patented medicines, in order to maintain a dominant market position, they are more likely to raise prices and restrict the circulation and development of medical technology. Therefore, the public health rights of poor developing countries cannot be guaranteed. Then there is an urgent need for a mandatory system to break down the barriers created by patent protection in response to the public interest. As a result, the medical patent compulsory licensing system is widely recognized as a solution.

3.2. Patent Compulsory Licensing System in Technical Field

The patent compulsory licensing system is not only needed in the medical field, but also in the technology application field. In order to promote the development and progress of patented technology and society, it will break through the limitation of patent protection law and form the patent compulsory licensing system in the technology application field. In the market, enterprises cannot obtain full profits in the market without the technical standards supported by patented technology. Therefore, in order to master more market share and gain a monopoly position. Enterprises have to continue upgrading technology, thereby consolidating their monopoly position. Ultimately, a technical standard is formed. While technical standards continue to absorb new patents, they are also endowed with exclusivity, which has a negative impact. For example, behaviors like restricting competition and technological progress, specifically, abusing market patent rights for market monopoly and price discrimination. Thus, to avoid the patent issues becoming a potential obstacle to trade, the patent compulsory licensing system will become an important decision.

4. Case Analysis

4.1. Case Overview

In 2006 and 2007, in response to AIDS, the Thai government successively issued compulsory licenses to several large foreign pharmaceutical companies. This makes the inexpensive generic medicines affordable to the poor people and effectively solves public health problems. This is a valid case for implementing a patent compulsory licensing system.

4.2. AIDS Public Health Issues in Thailand

In Thailand, a country where grief and pornography coexist, the porn industry exists legally. In 2002, a WHO statistical report on HIV/AIDS and sexually transmitted infections in Thailand reviewed that the exact proportion of HIV carriers in Thailand was 1.79%, and AIDS patients

reached 580,000. The serious HIV problem in many other countries has become an almost negligible thing in Thailand. Therefore, in terms of AIDS prevention and control work, Thailand bears an extremely heavy burden from the government to the people.

4.3. Implementation of Compulsory License System

Due to the backwardness of bio-pharmaceutical technology, local Thai pharmaceutical companies have no special-purpose medicines for AIDS. Patients can only take a cheap first-stage combination of medicines. Although cheap, they have large side effects and poor effects. Merck's Stocrin (trade name of efavirenz) works well, but the price is so expensive that ordinary income patients cannot afford it. Even worse, if the first-stage medicines taken for a long time, the patient will develop medicines resistance. And then, the second-stage medicines must be taken. Such as Abbott's patented medicines Coolidge (Kaletra, LOPINAVIR and Ritonavir compound pharmaceutical agent). The financial burden of patients is increasing, and the Thai government urgently needs to find an effective solution to relieve the high price of medicines burden and suppress the raging HIV virus.

In 2006, on the premise of not violating international regulations on compulsory licensing of patents, in accordance with the provisions of the Thai Compulsory Licensing Law, the Thai Public Health Department initially issued a five-year compulsory license and agreed on the mandatory licensing fee. However, the pharmaceutical companies were not willing to give up high profits, so they refused to accept the compulsory license, and declared that they were willing to cancel the compulsory license of the Thai government by way of price reduction. However, because the price reduction was extremely small, the Thai government rejected it. In particular, Abbott, which holds the patent rights of the second-stage medicine Coolidge, not only refused to negotiate, but also canceled the registration application for new medicines in Thailand in protest. But it was condemned by international AIDS prevention workers, especially under the intervention of WHO, Abbott protested to no avail and drastically reduced prices. At the same time, the Thai government indicated that even if the patented pharmaceutical company lowers the price of the medicines, the Thai government would firmly enforce the license. Unless the pharmaceutical company reduces the price of the generic medicines to the level of affordable generic medicines, the compulsory license can be withdrawn.

4.4. Opposition of Developed Countries

The Thai government's implementation of compulsory licensing of AIDS medicines patents has triggered dissatisfaction in developed countries led by the United States. It is believed that the implementation of this compulsory license system is a violation of the intellectual property system, which harms the interests of pharmaceutical companies and cracks down on the enthusiasm of pharmaceutical companies to study new medicines. And used this as an excuse to impose political, economic pressure on Thailand.

4.5. Discussion of the Implementation of Patent Compulsory Licensing System

As the first developing country to implement compulsory patent licensing system, Thailand's initiative has had a great impact. The essential contradiction between the Thai government's compulsory licensing measures and pharmaceutical companies is the power rank contradiction between the patent rights and the right to health. Both are basic rights in life, but under certain circumstances, we need to make a judgment which right has priority. Obviously, when public health issues occur, the right to health needs priority protection. Therefore, it is worth affirming that in

order to maintain public health issues, Thailand, as a developing country, under the great political and economic pressure from developed countries, has used detailed international and domestic laws to issue compulsory licenses. This approach guarantees the supply of cheap special-purpose medicines in the country and sets an example for other developing countries on how to save the lives of extremely poor patients.

Although this measure received a lot of support and praise, there is still room for discussion and progress. On the one hand, I believe that before the compulsory license is issued, the Thai government and the patented pharmaceutical company can negotiate friendly. That is to find a balance point, which can not only meet the profit needs of pharmaceutical companies, increase their enthusiasm for developing new medicines, but also reflect the social responsibility of pharmaceutical companies and still ensure that patients get high-quality cheap medicines. This balance can take into account the interests of both developed and developing countries and achieve a win-win situation. In particular, it can reduce the pressure on the disadvantaged developing countries to face developed countries. On the other hand, concerning the provision in Thailand's compulsory licensing regulations that "allows local production of the medicine", I think that a certain reason for the developed countries to express their opposition is that the implementation of compulsory licensing system will produce many cheaper generic medicines in the country, and export generic medicines to expand the market share. Further harm the interests of pharmaceutical patent companies and undermine the intellectual property system. Eventually, the exception of the intellectual property system evolved into a deformed normal.

5. Improvement of Compulsory License System in China

5.1. Current Situation and Deficiency of Legislation in China

The implementation of the compulsory license system in Thailand not only provides a new way of thinking for internationally addressing public health issues, but also enlightens many developing countries such as China. Compared with the whole process of the compulsory license of the Thai government, China's compulsory license system is too complicated.

The first is that the restrictions on applicants are too harsh. It is stipulated that applicants for compulsory license must be "units with implementation conditions", that is, applicants must be both units and capable of implementing authorized patents. This provision exceeds the restrictions on compulsory license applicants such as the TRIPS agreement, making the application of a compulsory license system less feasible in China. Secondly, the regulations on the reasons for compulsory license application are both vague and harsh. The harshness is reflected in China's legislation on compulsory license only stipulates that a few cases can apply for a compulsory license system, which shows that the implementation of compulsory license itself is restricted. But in fact, there are no specific restrictions on the use of compulsory license system in the TRIPS agreement and other agreements. Ambiguity is reflected in, for example, "for the purpose of public interest" can be used as a reason for compulsory license applications. However, in practical applications, definitions such as "public interest" are very abstract. Various units have different degrees of understanding, poor operability, and great ambiguity in application. Not only that, but the cumbersome procedures also discourage units that want to apply for compulsory licenses.

5.2. The Improvement of Compulsory License System in China

Therefore, I think that the country should relax restrictions, clarify some ambiguities in legislation, and enhance the operability of legislation. Specifically, relaxing the conditions and limitations of the applicants and relaxing the grounds for compulsory licensing applications will make

applications for compulsory licenses more flexible. At the same time, more detailed implementation rules and specific principles need to be given in explaining the reasons for compulsory licensing, and some important concepts should be clearly explained to enhance the operability of legislation.

6. Conclusion

In summary, the implementation of compulsory license system can not only curb the abuse of intellectual property system, but also promote technological progress and public interests. China's intellectual property protection system is still in the stage of legislative improvement, and compulsory license system has a long way to go in both legislation and practice.

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